

New Drug Manufacturer Report

Section	Data element	Field type	Drug #1
1. Drug identification	National drug code (11-digit NDC)	Numeric	16729-0430-43
	Drug name	Text	Argatroban in 0.9% Sodium Chloride 1 mg/ml (SDV)
2. Drug Launch Information	Description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally	Text	Marketing: Accord markets generic Argatroban in 1 pack and 10 pack vials. The drug is therapeutically equivalent to the innovator (brand) drug. As such, Accord relies on the safety and efficacy findings of the FDA with respect to the innovator drug. Accord does not interact with physicians and markets solely to distributors, hospital groups, group purchasing organizations and like entities based solely on price and availability. Accord does not market based on any aspects of the drug itself. Further, Accord does not aim to treat a certain number of patients, it simply looks at the size of the total market and aims to achieve a certain market share. Pricing: Accord Healthcare, Inc.'s pricing decisions regarding the WAC price of a medication are determined after consideration of many factors, including clinical and economic value of the particular therapy, therapeutic category, market dynamics, competitor pricing, discounts provided to customers in both the commercial and government channels, patient support to ensure patient access to life-saving and life-changing medications, overall research and development costs.
		Text	
	Estimated volume of patients who may be prescribed the drug	Numeric	N/A
	Whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval	Text	No
	Date and price of acquisition if the drug was not developed by the manufacturer	Text	N/A